STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

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December 30, 2020

Via e-filing at www.regulations.gov

Administrator Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-9914-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Comments regarding Proposed Rule, *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations*, 85 Fed. Reg. 78,572 (Dec. 4, 2020), RIN 1505-AC72 and RIN 0938-AU18.

Dear Administrator Verma:

The undersigned Attorneys General of the States of Delaware, Hawaii, Illinois, Iowa, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, and Washington, the Commonwealths of Massachusetts, Pennsylvania, and Virginia, and the District of Columbia ("the States") submit these comments regarding the Department of the Treasury's and Department of Health and Human Services' (collectively, "the Agencies") Proposed Rule, *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations*, 85 Fed. Reg. 78,572 (Dec. 4, 2020) (the "Proposed Rule"). The States write in opposition to a number of provisions contained in the Proposed Rule that are contrary to the purposes of the Patient Protection and Affordable Care Act ("ACA") or that will impose significant burdens on the States and on consumers during the ongoing pandemic.

Specifically, the Proposed Rule would incorporate the Agencies' improper 2018 guidance interpreting Section 1332 of the ACA into regulations, undermine access for limited English proficiency populations, and evade the legal requirements of the ACA by permitting states to adopt a Direct Enrollment option without seeking and receiving necessary waivers and by permitting the use of web-broker non-Exchange websites despite consumer protection concerns. The Proposed Rule would also result in unnecessary increases in costs to the States while reducing funding available to support the operations of the Exchanges, increase out-of-pocket

costs to consumers, and usurp the States' role in enforcement within their own State-Based Exchanges. Finally, the Agencies fail to provide a sufficient comment period for a Proposed Rule of this complexity and significance. We urge the Agencies to withdraw these provisions of the Proposed Rule immediately.

I. Several Provisions of the Proposed Rule are Contrary to the Purposes of the ACA

The Proposed Rule includes a number of proposals that are contrary to requirements under the ACA. First, the Agencies propose to codify their improper 2018 guidance in which they erroneously interpreted Section 1332 of the ACA.[1] Second, the Agencies propose to permit states to adopt a Direct Enrollment ("DE") option without requiring states to comply with the process required by Section 1332.[2] Third, the Agencies propose to permit the use of non-exchange web-broker websites in contravention of the purpose of the ACA's Exchanges.[3] Finally, the Agencies propose to grant Enhanced Direct Enrollment ("EDE") websites a grace period of 12 months, during which the website would not need to comply with translation requirements.[4]

A. Incorporation into Regulation of 2018 Section 1332 Guidance

Section 1332 of the ACA permits states to seek federal approval for waiver of certain ACA requirements, as long as the state seeking the waiver demonstrates that its proposal satisfies a number of guardrails identified in the statute. The intended purpose of Section 1332, as reflected in the Agencies' initial 2015 interpretation of that provision,[5] was to ensure that a Section 1332 waiver would not reduce the number of state residents to whom affordable and comprehensive coverage would be provided below a level comparable to the number of state residents who would be provided such coverage absent the waiver. The Agencies' 2015 guidance further interpreted Section 1332 to prohibit waivers that would reduce the comprehensiveness and/or affordability of coverage for vulnerable populations, thereby furthering the ACA's core purpose of providing consumers access to affordable and comprehensive health coverage.[6]

The Agencies' 2018 guidance reinterpreted the Section 1332 guardrails as being met as long as "access to coverage that is as affordable and comprehensive as coverage forecasted to have been available in the absence of the waiver is projected to be available to a comparable number of people under the waiver," regardless of the affordability or comprehensiveness of coverage that is actually obtained by residents of the state.[7] The 2018 guidance also permitted state waivers that made coverage less comprehensive or affordable for particular sub-groups of residents, including vulnerable populations, as long as access to affordable and comprehensive coverage was not reduced for the population as a whole.[8] The 2018 guidance represented a

[1] 85 Fed. Reg. at 78,648-49
[2] *Id.* at 78,619.
[3] *Id*. at 78,611.
[4] *Id.* at 78,610.
[5] Waivers for State Innovation, 80 Fed. Reg. 78,131 (Dec. 16, 2015).
[6] *Id*.
[7] State Relief and Empowerment Waivers, 83 Fed. Reg. 53,575 (Oct. 24, 2018).
[8] *Id*.

substantial deviation from the statutory provisions of Section 1332 and undercut the purpose of the ACA to enhance access to affordable and comprehensive health coverage. The Agencies' proposal to codify that guidance should thus be rejected.

B. The Proposed Direct Enrollment Option Violates Requirements Established by Section 1332 of the ACA

The Agencies propose to facilitate a shift from Exchanges to private-sector options, subject to Department of Health and Human Services ("HHS") approval, in any state that chooses to do so. Specifically, the Proposed Rule includes proposed 45 CFR § 155.221(j), which would permit states to choose an Exchange Direct Enrollment option, in which states could adopt a private-sector-based enrollment option as an alternative to the Exchange.[9] States operating State-Based Exchanges ("SBE") could adopt a DE option beginning in 2022, while those utilizing a Federally Facilitated Exchange ("FFE") or a State-Based Exchange relying on the federal platform ("SBE-FP") could adopt the DE option beginning in 2023.[10]

In essence, the Agencies propose that each state be permitted to mimic Georgia's recent move to eliminate the use of HealthCare.gov and replace it with a decentralized system of enrollment through web-brokers and insurers. That plan, proposed by Georgia in December of 2019 and modified in July of 2020, was approved by the Centers for Medicare and Medicaid Services ("CMS") in November of 2020.[11] Consistent with the requirements of Section 1332, Georgia's proposal went through public notice and comment at the state level, including public hearings, and subsequently went through a public notice and comment period at the federal level.[12] CMS approved Georgia's waiver only after all statutory requirements of Section 1332 were met, and the state received a waiver of Sections 1311(b), (c), (d), (e), and (i) of the ACA.[13] In contrast, the Agencies' Proposed Rule would improperly permit states to adopt a Direct Enrollment option without (a) satisfying the requirements of Section 1332 by submitting a formal waiver request, and (b) obtaining a waiver of provisions that are in direct conflict with the DE option.

In their proposal, the Agencies state that there are no provisions of the ACA that must be waived in order for states to adopt a Direct Enrollment option as envisioned in their Proposed Rule. The Agencies argue that the ACA does not require the states or the federal government to operate an enrollment website, relying on Section 1311(d)(4) of the ACA.[14] The Agencies further interpret Sections 1311(c)(5) and 1311(d)(4) of the ACA to require only that Exchanges provide consumers with the ability to view comparative information on qualified health plan ("QHP") options, while allowing Exchanges to direct consumers to other entities for the purposes of submitting applications for and enrolling in QHPs.[15]

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[9] 85 Fed. Reg. at 78,619.
[10] *Id*. at 78,621.
[11] CMS Letter Approval (Nov. 1, 2020), https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-/1332-GA-Approval-Letter-STCs.pdf.
[12] *Id*.
[13] Katie Keith, *The 2022 Proposed Payment Notice, Part 1: Exchange Provisions*, HEALTH AFFAIRS (Nov. 27, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201127.118789/full/.
[14] 85 Fed. Reg. at 78,620; 42 U.S.C. § 18031(d)(4).
[15] 85 Fed. Reg. at 78,620.

The Agencies do not have the authority to permit a state to adopt a Direct Enrollment option without adhering to the processes provided for in Section 1332 of the ACA. Under Sections 1103 and 1311 of the ACA, the HHS Secretary is required to operate, maintain, and update an internet portal, and to assist states in developing and maintaining their own internet portals, which include a mechanism for consumers to receive information on coverage options, obtain standardized comparative information, and make available QHPs to individuals and employers. The ACA specifically requires each state to establish an Exchange—a governmental agency or nonprofit entity established by the state—that facilitates the purchase of qualified health plans.[16] And the Exchange, in turn, is required to actually "offer coverage"—that is, make QHPs available to qualified individuals and qualified employers—not simply to provide information on available options that individuals and employers must then obtain elsewhere.[17]

The Agencies' current proposal to allow states to adopt the DE option without going through the Section 1332 waiver process also conflicts with the methodical approach CMS took with the State of Georgia, under which both Georgia and CMS adhered to the requirements of Section 1332, and CMS explicitly granted waivers of multiple sections of the ACA. Indeed, Georgia was granted a waiver of Sections 1311(b), (c), (d), (e), and (i) of the ACA because those provisions were in direct conflict with Georgia's planned Direct Enrollment option.

In addition to circumventing the statutory requirements of Section 1332, the Agencies also essentially revise the interpretation of Exchanges as defined in 45 CFR § 155.20 without actually proposing to formally do so as required by law.[18] Without seeking to formally amend the term Exchanges as defined by statute, the Agencies reinterpret the term to include State-Based Exchanges (SBE), Federally Facilitated Exchanges (FFE), State-Based Exchanges relying on the federal platform (SBE-FP), and new private-sector Direct Enrollment Exchanges.[19] This interpretation is not supported by the plain terms of Section 155.20, which defines an Exchange as a "governmental agency or non-profit entity" meeting specified standards and making QHPs available to qualified individuals and/or qualified employees.[20]

The States also note that, while Direct Enrollment options have been available for a number of years, enrollments through those options account for only one-third of all FFE enrollments.[21] It is concerning to the States that the Agencies propose to allow states to eliminate their own Exchanges or their use of HealthCare.gov, through which most individuals enroll, and to instead utilize the Direct Enrollment option that has proven less popular for enrollment.

[16] 42 U.S.C. § 18031(b)(1)(A).
[17] 42 U.S.C. §§ 18031(d)(1), (2).
[18] 85 Fed. Reg. at 78,610.
[19] *Id.*
[20] 45 CFR § 155.20.
[21] Keith, *supra* note 13.

C. Use of Web-Broker Non-Exchange Websites for QHP Selection and Enrollment

The Agencies propose permitting Navigators and Certified Application Counselors ("CACs") in an FFE or SBE-FP to use web-broker, non-Exchange websites while assisting consumers with their applications for insurance affordability programs and qualified health plan enrollment under specified circumstances and as permitted by state law.[22]

To permit Navigators and CACs in FFE and SBE-FP states to rely on web-broker non-Exchange websites, the Agencies propose to amend 45 CFR § 155.220 to require such websites to display all QHP data provided by the Exchange and to identify for consumers any QHPs for which the web-broker non-Exchange website does not facilitate enrollment, including a disclaimer providing information about enrollment through an Exchange-operated website.[23]

The Agencies also propose an additional amendment to 45 CFR § 155.220 that would require web-broker non-Exchange websites not available for use by Navigators and CACs to provide only limited information on QHPs for which the website does not support enrollment. This information would be limited to the issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information.[24]

The States express a number of concerns regarding the use of web-broker non-Exchange websites and note that their use directly undermines the ACA's purpose in establishing Exchanges to allow consumers to directly compare all available plans and to easily determine their eligibility for Medicaid and for subsidies. In particular, whereas Exchanges provide information only for plans that are ACA-compliant, web-broker non-Exchange websites offer plans that do not meet ACA requirements and can use screening tools that direct consumers away from marketplace options or ACA-compliant plans.[25] Web-broker non-Exchange websites also impose barriers on individuals who are eligible for Medicaid or for other programs or subsidies by failing to inform them of their eligibility.[26] Moreover, whereas Exchanges identify all available options and allow consumers to directly compare them, web-broker non-Exchange websites do not necessarily present all options available to a consumer or present available plans in a way that allows for direct comparison of plans based on price and quality.[27]

D. Grace Period for Compliance with Translation Requirements

The Agencies propose to allow issuers of qualified health plans and web-brokers who choose to participate in the FFE Enhanced Direct Enrollment option to have a 12-month grace period during which the issuer or broker would not need to comply with website content translation requirements.[28] Those requirements currently ensure that issuer and broker websites

[22] 85 Fed. Reg. at 78,611.
[23] *Id*. at 78,613.
[24] *Id*. at 78,615.
[25] Tara Straw, *"Direct Enrollment" in Marketplace Coverage Lacks Protections for Consumers, Exposes them to Harm*, CTR. ON BUDGET & POL'Y PRIORITIES (March 15, 2019), https://www.cbpp.org/sites/default/files/atoms/files/3-15-19health.pdf.
[26] *Id*.
[27] *Id*.
[28] 85 Fed. Reg. at 78,610.

are translated into any non-English language spoken by a limited English proficient ("LEP") population making up 10% or more of the state in which it is operating.[29] The Agencies assert that the proposal would provide an incentive for insurers and web-brokers to enter markets with significant LEP populations by permitting them to test markets before incurring translation costs.[30]

The delay in translation requirements threatens to deprive LEP populations of meaningful access in violation of the non-discrimination provisions in Section 1557 of the ACA.[31] According to the latest American Community Survey 5-Year Estimates, the percentage of the U.S. population classified as speaking English "less than very well" is 8.4 percent, while the percentage of people who speak a language other than English at home is 21.6 percent.[32] A recent study, published in December 2020, found that even after the implementation of the ACA, LEP populations continued to lag behind populations that speak English only in terms of the proportion of individuals who have obtained health insurance.[33] A move to a decentralized system of enrollments through web-brokers and insurers that grants a 12-month delay in website content translation requirements would further reduce access to a vulnerable population already struggling with meaningful access.

II. The Proposed Rule Includes Several Onerous and Misguided Requirements

In addition to numerous aspects of the Proposed Rule that are contrary to the ACA's purposes, the Proposed Rule also imposes burdensome and misguided requirements, particularly in the midst of the ongoing pandemic. These proposals include requiring Exchanges to increase verification of special enrollments;[34] increasing the premium adjustment percentage for 2022;[35] reducing marketplace user fees generated by HHS;[36] and increasing HHS' authority to conduct audits and compliance reviews, and impose monetary penalties, on state Exchanges.[37]

A. Proposal to Increase Special Enrollment Period Verification Requirements on State Exchanges

In its Proposed Rule, the Agencies seek to amend 45 CFR § 155.420 to include a new provision requiring State Exchanges to conduct eligibility verification for special enrollment periods for at least 75 percent of new enrollments during those periods.[38] The Agencies acknowledge in their proposal that this requirement would cost State Exchanges approximately $108 million over the course of 2021 through 2023 and ongoing costs of around $1.4 million in

[29] *Id.*
[30] *Id.* at 78,611.
[31] 42 U.S.C. § 18116.
[32] U.S. Census Bureau, 2015-2019 American Community Survey 5-Year Estimates.
[33] Andriana M. Foiles Sifuentes, Monica Robledo Cornejo, Nien Chen Li, Maira A. Castaneda-Avila, Jennifer Tjia, & Kate L. Lapane, *The Role of Limited English Proficiency and Access to Health Insurance and Health Care in the Affordable Care Act Era*, HEALTH EQUITY, Dec. 2020, at 509.
[34] 85 Fed. Reg. at 78,628-29.
[35] *Id.* at 78,633.
[36] *Id.* at 78,629-32.
[37] *Id.* at 78,638.
[38] *Id.* at 78,628.

2024 and 2025.[39] The proposal would impose a needless burden and cost on State Exchanges due to federal cutbacks to funding for states to provide marketplace advertising and consumer assistance. This effect on State Exchanges would only be compounded by the current pandemic, which has driven up the number of individuals eligible to enroll during special enrollment periods due to loss of employment or loss of income. Given the cost and the burden on State Exchanges, the proposal to increase special enrollment period verifications on State Exchanges should be withdrawn.

B. Proposal to Increase Premium Adjustment Percentage

The Agencies propose to increase the annual premium adjustment percentage, used to set the rate for the maximum annual limit on cost-sharing and the required contribution percentage for exemption eligibility, among other things. In 2015, CMS adopted a methodology to determine the premium adjustment percentage based on employer-sponsored premium data from the National Health Expenditure Account.[40] However, CMS chose to update this methodology for the 2020 plan year to include increases in individual market premiums in addition to relying on employer-sponsored premium data; the change in methodology resulted in a higher premium adjustment percentage and a higher annual limit on cost-sharing.[41] That change affected millions of individuals with plans with out-of-pocket limits at or near the maximum at that time, and it disproportionately affected those with pre-existing conditions, who are likely to reach the out-of-pocket limits on their plans.[42]

The Agencies' proposal for the 2022 plan year maintains the same methodology adopted in the 2020 plan year, resulting in a premium risk adjustment percentage for 2022 of 1.4409174688.[43] Based on this methodology, the Agencies propose an increase in the maximum annual limit of cost-sharing of 6.4% over the 2021 limit, from $8,550 to $9,100 for self-only coverage and from $17,100 to $18,200 for other than self-only coverage.[44] Further increasing the maximum annual limit on cost-sharing for 2022 over that imposed in 2021 will further disproportionately affect those with pre-existing conditions, including millions facing long-term health effects in the years to come as a consequence of the current COVID-19 pandemic, and, as such, the Agencies should withdraw this proposal.

C. Proposal to Reduce the Collection of Marketplace User Fees

Section 1311(d)(5)(A) of the ACA permits a state operating an Exchange to charge user fees on participating health insurers to help support the operations of the Exchange. For states that do not operate an Exchange and instead rely on an Exchange operated by HHS within the

[39] *Id.* at 78,655.
[40] *Id.* at 78,633; Keith, *supra* note 13; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015, 79 Fed. Reg. 13,743 (March 11, 2014).
[41] Keith, *supra* note 13; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17,454 (Apr. 25, 2019).
[42] Aviva Aron-Dine & Matt Broaddus, *Change to Insurance Payment Formulas Will Raise Costs for Millions with Marketplace or Employer Plans*, CTR. ON BUDGET & POL'Y PRIORITIES (April 26, 2019), https://www.cbpp.org/sites/default/files/atoms/files/1-18-19health.pdf.
[43] 85 Fed. Reg. at 78,633.
[44] *Id.*

state, 45 CFR 156.50(c) provides that any participating health insurers offering plans through an FFE or SBE-FP must pay a user fee to HHS each month based on a formula taking into consideration the annual user fee rate as determined by HHS and the monthly premium charged by the insurer for each policy with enrollment through an FFE or SBE-FP.[45] For the 2022 plan year, the Agencies have proposed a reduction in user fee rates for insurers offering plans through an FFE from 3% to 2.25% and a reduction in user fee rates for insurers offering plans through an SBE-FP from 2.5% to 1.75%.[46] The Agencies also propose a user fee rate of 1.5% for states that choose to implement the proposed direct enrollment option beginning in the 2023 plan year.[47] The States urge the Agencies to withdraw the proposed user fee reductions, as they would significantly reduce the fees used to fund operations, including maintenance of HealthCare.gov, outreach, the Navigator program, and plan management functions, significantly limiting marketplace functionality, consumer assistance, and marketing.

D. Proposal to Increase HHS Authority to Conduct Audits and Compliance Reviews of and Impose Civil Monetary Penalties through State Exchanges

In its Proposed Rule, the Agencies propose to consolidate HHS' audit authority under 45 CFR § 156.480(c) to capture user fee audits by HHS, in addition to its audit authority over advance premium tax credits ("APTC") and cost-sharing reduction ("CSR") payments to issuers of qualified health plans.[48] The Agencies also propose several amendments to 45 CFR § 156.480(c) which would expand HHS' oversight tools to include compliance reviews of issuers of qualified health plans rather than just traditional audits.[49]

In addition, the Agencies propose amendments to allow HHS to enforce compliance regardless of Exchange type where states fail "to substantially enforce" applicable standards relating to APTC, CSRs, and user fees.[50] Specifically, the Agencies propose to amend 45 CFR § 156.480(c) to codify that HHS has the ability to enforce applicable standards relating to APTC, CSRs, and user fees if a State Exchange or SBE-FP failed to substantially enforce these requirements and to clarify that HHS would use the same standards and processes it uses for enforcement against insurers participating in an FFE, outlined in 45 CFR §§ 156.805 and 156.806.[51] This would include an amendment to reflect HHS' authority to impose civil monetary penalties against insurers participating in a State Exchange or SBE-FP.[52]

The proposals would provide HHS with significant authority to conduct oversight against not only insurers participating in an FFE, but also against those participating in State Exchanges or SBE-FPs. While the States generally support enhanced oversight of insurers' compliance with the ACA, the Agencies' proposal would improperly usurp the States' role in enforcing applicable standards within their own State-Based Exchanges. Accordingly, the States urge the Agencies to withdraw these proposals.

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[45] *Id*. at 78,629.
[46] *Id*. at 78,630.
[47] *Id*.
[48] *Id*. at 78,638.
[49] *Id*.
[50] *Id*.
[51] *Id*. at 78,640.
[52] *Id*.

III. The December 30th Deadline for Comments Is too Early to Provide an Opportunity for a Meaningful Comment Period

Finally, the States express concerns with the timeline set by the Agencies for responding to their Proposed Rule. The Proposed Rule was published on December 4, 2020, and the Agencies imposed a deadline for comments of December 30, 2020 at 5:00 P.M, providing only a 26-day comment period. The Administrative Procedure Act ("APA") requires that agencies provide "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments…."[53] The Executive Branch has interpreted this requirement to mean that a sixty-day comment period, at a minimum, is necessary to allow interested parties to have a meaningful opportunity to comment on proposed regulations.[54]

The Agencies' Proposed Rule is complicated and the proposals that it contains will have a significant impact on the economy and will impose significant economic burdens on the States. In the Proposed Rule, HHS acknowledges that the proposal is a "significant rule" that will have economic impacts of $100 million or more in at least one year.[55] A comment period of only 26 days is insufficient for interested parties to provide meaningful comment on a significant Proposed Rule, particularly given that the 26-day period includes the holiday season.

* * *

The States have identified a number of proposals issued by the Agencies in their Proposed Rule that would result in excessive burdens or costs to consumers or the States, costs that are only compounded by the Agencies' proposal to inflict them on states during a pandemic and on consumers with pre-existing conditions, an ever-growing population due to COVID-19. The States also identify a number of proposals that directly contradict the statutory requirements of the ACA or otherwise undermine the ACA's stated purposes. The States further reiterate their concern that the Agencies' deadline for comment is too early to allow for a meaningful comment period, as required by the APA. The States urge the Agencies to withdraw these provisions of the Proposed Rule.

Sincerely,

Letitia James

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[53] 5 U.S.C. § 553(c).
[54] *Regulatory Planning & Review*, Exec. Order 12,866, § 6(a)(1) (Sept. 30, 1993) (stating that, in most cases, a meaningful opportunity to comment on a proposed regulation should include a comment period of not less than 60 days); *Improving Regulation and Regulatory Review*, Exec. Order 13,563 (Jan. 18, 2011) (reiterating that an agency should generally provide the public with at least a 60-day comment period to allow the public to have a meaningful opportunity to comment on a proposed regulation).
[55] *Id*. at 78,654.

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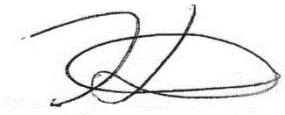

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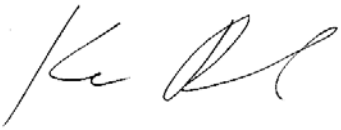

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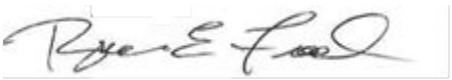

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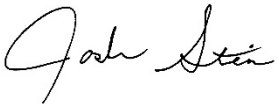

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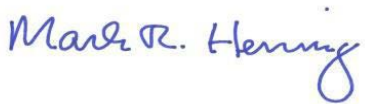

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